Joint Meeting of the Anesthetic Life Support Drugs Advisory Committee (ALSDAC) and Drug Safety & Risk Management Advisory Committee (DSaRM)
Holiday Inn, Gaithersburg
Two Montgomery Village Avenue, Gaithersburg, MD.
September 23, 2009

Summary Minutes

All external requests for the meeting transcripts should be submitted to the CDER, Freedom of Information office.

These summary minutes for the September 23, 2009 Meeting of the Joint Anesthetic Life Support Drugs and Drug Safety and Risk Management Advisory Committee Meeting of **the Food and Drug Administration were approved on __October 15, 2009_**

I certify that I attended the September 23, 2009 meeting of the Joint Anesthetic Life Support Drugs and Drug Safety and Risk Management Advisory Committee Meeting of the Food and Drug Administration and that these minutes accurately reflect what transpired.

_____/s/_____
Kalyani Bhatt
Designated Federal Official, ALSDAC

_____/s/_____
Jeffrey R. Kirsch, M.D.
Committee Acting Chair

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Summary Minutes

The Joint Anesthetic Life Support Drugs and the Drug Safety and Risk Management Advisory Committee Meeting of the Food and Drug Administration met on September 23, 2009 at the Holiday Inn, Gaithersburg, Two Montgomery Village Avenue, Gaithersburg, Maryland. Jeffrey R. Kirsch, M.D. was the acting chair for the meeting. There were approximately 150 persons in attendance. There were 5 speakers for the Open Public Hearing Session

Attendance:

Anesthetic and Life Support Drugs Advisory Committee Members Present (voting)
Jayant K. Deshpande, M.D., Jeffrey R. Kirsch, M.D. (Acting Chair)

Industry Representative for Anesthetic and Life Support Drugs (non-voting):
Bartholomew Tortella, M.D., M.T.S, M.B.A.

Drug Safety and Risk Management Advisory Committee Members Present (voting)
Elaine Morrato, DrPH, M.P.H., C.P.H., Allen J. Vaida, Pharm.D, FASHP

Anesthetic and Life Support Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee Consultants (Temporary Voting Members):
Edward Covington, M.D., Richard A. Denisco, M.D., M.P.H., Randall Flick, M.D., Timothy S. Lesar, Pharm.D, Karl Lorenz, M.D., M.S., H.S., John Markman, M.D., Martha Solonche (Patient Representative), Michael L. Yesenko (Patient Representative), Julie Zito, Ph.D.

Anesthetic and Life Support Drugs Advisory Committee Members Absent:
Sorin J. Brull, M.D., Osemwota A. Omoigui, M.D., Julia Pollack, M.D., Donald S. Prough, M.D. Daniel Zelterman, Ph.D., Robert K. Stoelting, M.D., Athena F. Zuppa, M.D.

Drug Safety and Risk Management Advisory Committee Members Absent:
D. Bruce Burlington, M.D., Sander Greenland, Dr.PH., Susan Heckbert, M.D., Ph.D., Lewis Nelson, M.D., Sidney Wolfe, M.D.

Open Public Speakers:
Mary Baluss, Denise S. Zamora, Robert Lund, Patricia O'Hara, Elizabeth Turner Whalen

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee (ALSDAC) and Drug Safety & Risk Management Advisory Committee (DSaRM)

AGENDA

The committee will discuss new drug application (NDA) 21-217, EXALGO (hydromorphone HCl), Neuromed Pharmaceuticals, Inc., and its safety for the proposed indication of treatment of moderate-to-severe pain in opioid tolerant patients

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Call to Order Introduction of Committee	**Jeffrey Kirsch, MD** Chair, ALSDAC
Conflict of Interest Statement	**Kalyani Bhatt** Designated Federal Officer, ALSDAC
Opening Remarks	**Ellen Fields, MD, MPH** Clinical Team Leader, Division of Analgesia, Anesthesia, and Rheumatology Products (DAARP), CDER/FDA
Sponsor Presentations	
Introduction / Clinical Pharmacology/ Closing Remarks	**C. Eugene Wright, PharmD, PhD** Vice President, Project Leadership Neuromed Pharmaceuticals, Inc.
Regulatory Overview	**James Ottinger, RPh** Vice President, Regulatory Affairs Premier Research Group
Clinical Overview	**Christopher Gallen, MD, PhD** Chief Executive Officer Neuromed Pharmaceuticals, Inc.
Extended Release Hydromorphone	**Lynn R. Webster, MD, FACPM, FASAM** Medical Director Lifetree Clinical Research and Pain Clinic
Exalgo Alliance: Risk Evaluation & Mitigation Strategy (REMS)	**Annette Stemhagen, DrPH, FISPE** Senior Vice President Epidemiology, Registries and Risk Management United BioSource Corporation

Exalgo Alliance: Implementation, Assessment and Commitment	**Herbert Neuman, MD** Vice President and Chief Medical Officer Covidien
Questions for Presenters	
FDA Presentations	
Clinical Review of EXALGO	**Elizabeth Kilgore, MD** Medical Officer DAARP, CDER/FDA
Drug Utilization Trends	**Patty Greene, PharmD** Drug Utilization Analyst Division of Epidemiology (DEPI) OSE, CDER/FDA
Findings from the Drug Abuse Warning Network (DAWN)	**Catherine Dormitzer, PhD** Epidemiologist Division of Epidemiology (DEPI), OSE, CDER/FDA
EXALGO Abuse Liability	**Jianping Gong, MD, PhD** Medical Officer Controlled Substance Staff (CSS), CDER/FDA
EXALGO Risk Management: Postmarketing Experience and Recommendations	**Jeanne Perla, PhD** Risk Management Analyst Division of Risk Management OSE, CDER/FDA
Open Public Hearing	
Questions to the presenters	
Discussion and Questions to the Committee	
Adjourn	

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Draft Questions to the Committee

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1. Discuss where Exalgo lies in the spectrum of risk for abuse, including abuse-related overdose and death, compared to other opioid drug products.

   The committee consensus was that the drug Exalgo is a significantly efficacious drug for a group of opiate tolerant patients. It also has a significant potential for abuse because, like the other opiates, it is very potent, with a high level of subjective liking on the part of addicts. In the spectrum of abuse, it is towards the top of the spectrum of the drugs that are currently in the market. It is reasonable to predict that the abuse of Exalgo will parallel its availability, much like Oxycontin.

2. Based on your assessment of the risk associated with abuse of Exalgo, discuss which of the following options would be appropriate for risk management:

   a. A program similar to Onsolis, including registration for physicians and patients

   b. An opioid class-like program including physician education and registration, but no patient registry and, in the short term, an interim REMS pending the larger opioid class program as was done with Embeda

   c. A unique program

   The Committee endorsed the REMS Program as outlined by the sponsor, with the caveat that it should be accomplished in combination with a phased-in introduction of Exalgo into the market. The program should assure that the drug is first prescribed by a particular set of practioners or provider types, and only in a designated patient population/disease type. A careful phased-in rollout maximizes the potential that this valuable drug enters the market in a way that it allows it to maintain a sustained presence.

   The meeting adjourned at 3:30 PM.